

REMARKS

In the Office Action, the Specification is objected to; Claims 1-16 are rejected under 35 U.S.C. § 112, second paragraph; and Claims 1-16 are rejected under 35 U.S.C. § 102. The Specification has been amended.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **“Version with Markings to Show Changes Made.”** Applicants respectfully submit that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

In the Office Action, the Patent Office has objected to the Specification. The Patent Office essentially asserts that a number of trademark terms identified on page 2 of the Specification have not been capitalized. As previously discussed, Applicants have amended the Specification. In view of same, Applicants believe that all trademarks or trade names recited in the Application have been capitalized. To the further extent that the Patent Office believes there are any trademarks or trade names that are not capitalized, Applicants respectfully request that the Patent Office point out same.

Accordingly, Applicants respectfully request that this objection be withdrawn.

In the Office Action, Claims 1-16 are rejected under 35 U.S.C. § 112, second paragraph. More specifically, the Patent Office alleges that Claims 1-3 are indefinite in the recitation “a protein mixture which ...” because it is not clear what kind of protein mixture the claims are referring. Further, the Patent Office alleges that Claim 7 is unclear in the recitation “... having a molecular weight of less than 1,000 Da ...”, “... having a molecular weight of 1,000 Da to 5,000 Da ...” and “... having a molecular weight of greater than 5,000 Da” because the claim allegedly recites three different ranges in one claim. Applicants believe that the rejection of the claims under 35 U.S.C. § 112, second paragraph is improper set forth in detail below.

With respect to Claims 1-3, Applicants believe that the claim term “a protein mixture which simulates the amino acid profile of whey protein” is clear and definite in meaning as fully supported in the Specification. As defined, one skilled in the art would clearly understand this term to mean a protein mixture that has an amino acid profile that is similar (e.g., simulates) to or has the same amino acid profile of whey protein. For example, the protein mixture can include a mixture of proteins, protein hydrolysates and/or free amino acids as clearly supported in the Specification on page 4 at lines 7-11.

With respect to Claim 7, this claim defines a concise weight distribution of the hydrolyzed whey protein. Claim 7 recites that the hydrolyzed whey protein contains specified amounts of free amino acids, peptides with a molecular weight less than 1,000 Da, peptides with a molecular weight that ranges from 1,000 Da to 5,000 Da and peptides with a molecular weight greater than 5,000 Da. In this regard, one skilled in the art would clearly understand the scope and meaning of the hydrolyzed whey weight distribution as defined in Claim 7. Moreover, it is entirely appropriate to use terms such as "less than" and "greater than" as required in Claim 7. Therefore, Applicants believe that Claims 1-16 fully comply with 35 U.S.C. § 112, second paragraph.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, Claims 1-16 are rejected under 35 U.S.C. § 102. More specifically, Claims 1-16 are rejected in view of International Patent Publication No. WO 98/54985 or U.S. Patent No. 5,849,335 ("*Balleve*"). Applicants respectfully submit that these rejections are improper.

With respect to the anticipation rejection in view of WO 98/54985, Applicants believe that this reference should be precluded as prior art. In this regard, the earliest effective prior art date of WO 98/54985 is the publication date of December 10, 1998, whereas the above-identified patent application claims priority to an application filed on March 31, 1998. Therefore, the WO 98/54985 publication should not be considered prior art with respect to the above-identified patent application.

In any event, the WO 98/54985 reference uses a completely different protein source for providing glutamine as compared to the protein source of the claimed invention which requires a whey protein or a protein mixture that has an amino acid profile similar to whey protein. Indeed, an advantage of the WO 98/54985 reference is that the nutritional product contains a protein source which is less expensive than casein and whey. See, WO 98/54985, page 3, lines 10-12. Therefore, Applicants believe that this reference fails to anticipate or arguably render obvious the claimed invention.

With respect to the *Balleve* reference, Applicants believe this reference fails to disclose or suggest a number of features of the claimed invention. For example, nowhere does this reference disclose or arguably suggest the protein source feature of the claimed invention. Each of the independent Claims 1, 2 and 3 require administering a nutritional composition with a

protein source of whey protein or a protein mixture with an amino acid profile that is similar to whey protein. Applicants have discovered that this type of protein source is effective for increasing plasma glutamine concentration in a stressed mammal (see, Claim 1), for increasing muscle glutamine concentrations in a mammal (see, Claim 2) and/or for providing glutamine to a mammal suffering from injured, diseased or under-developed intestines (see, Claim 3).

In contrast, the clear emphasis of the *Ballevre* reference relates to the use of a carob protein to provide a source of glutamine. See, *Ballevre*, column 2, lines 38-46. Indeed, this reference only optionally discloses that other types of protein in addition to carob protein, such as casein, whey or free amino acids, can be used. However, nowhere does this reference disclose or arguably suggest that the use these other types of proteins can be effectively used as a source of glutamine for increasing plasma glutamine concentration in a stressed mammal, for increasing muscle glutamine concentrations in a mammal and/or for providing glutamine to a mammal suffering from injured, diseased or under-developed intestines as required by the claimed invention. For at least these reasons, Applicants do not believe that the *Ballevre* reference anticipates or arguably renders obvious the claimed invention.

Accordingly, Applicants respectfully request that the anticipation rejections be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the patent application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Another method of supplementing diet with glutamine has centred on the use of gluten or gluten hydrolysates as a protein source for nutritional compositions. Gluten is particularly rich in glutamine and is hence a good source of glutamine. Also, the use of gluten or a gluten hydrolysate offers the advantage of providing the glutamine in a form which is stable and relatively soluble. However gluten is potentially allergenic and this has severely limited its use in nutritional formulas. This problem may be ameliorated to some extent by using a gluten hydrolysate instead of a gluten and a nutritional composition based on gluten hydrolysate are commercially available under the trade names ~~Nutricomp~~NUTRICOMP®, ~~Immun~~IMMUN, ~~Reconvan~~RECONVAN® and ~~Glutasorb~~GLUTASORB®. However, although the risk from allergenic reaction is much reduced, it has not been removed entirely.